

### **REMARKS**

Following entry of the foregoing amendments, claims 38-39 and 42-55 constitute the pending claims in the present application. Claims 1-37 and 40-41 are cancelled. Claims 42-55 are new.

#### **Acknowledgement of Non-Responsive Amendment and Status of Pending Claims**

Applicants acknowledge Office's position that the amendment mailed August 2, 2005 is considered non-responsive for allegedly canceling all claims drawn to the elected invention and presenting only claims drawn to a non-elected invention, in vitro methods for inhibiting cell proliferation. Applicants also appreciate the telephone discussion with Examiner Badio on November 1, 2005, which clarified the situation.

Pursuant to MPEP 821.03, the non-responsive amendment mailed August 2, 2005 should not have been entered. Accordingly, Applicants' amendments herein are based on the claims as pending prior to the filing of this amendment, and Applicants arguments herein are in reference to the Office Action of February 2, 2005, the last substantive Action.

#### **Claim Amendments and New Claims**

Applicants acknowledge in the outstanding Office Action of February 2, 2005 that the Examiner notes that the claimed invention is allowable to the extent that it reads on the elected Group, *i.e.*, "the method as claimed by the instant claims utilizing compounds having the chemical skeleton as cyclopamine or jervine." As such, Applicants are amending claims 38-39 to recite the elected compounds and subject matter of claim 1 and are thus cancelling claim 1. Claim 39 is also amended to further recite the elected compounds, such as those depicted in Formula II on page 35 of the specification. Furthermore, claim 39 and the specification are amended to recite that R5 may be "absent" in occurrences of Formula II and sub-formulas thereof. The omission of "absent" from the specification is an obvious error as it can be seen that in order for the double bond to be present between the carbons bearing R5 and R6 that R5 must necessarily be absent. The structures of jervine and cyclopamine, to which the pending claims have been restricted, further demonstrate that R5 is absent when the double bond between the carbons bearing R5 and R6 is present. These amendments rectify the obvious omission of this possibility for R5. Applicants submit that these amendments present no new matter.

New claims 42-43 and 45-48 are dependent from claims 38 and 39 and recite further limitations thereon. Support for these claims can be found in the specification, for example, on pages 34-36. These claims present no new matter. Applicants are cancelling claims 22 and 27 and representing as claim 44. Claims 20, 28, and 36 are cancelled without prejudice. Applicants are cancelling claims 15-17 and resubmitting as new claims 49-51. Similarly, claims 41, 23, and 37 are cancelled and substantially represented as claims 52, 53, and 54, respectively. New claim 55 has support in numerous places in the specification, for example on page 80, lines 19 and 28-29. These amendments present no new matter.

Applicants submit that since the Office has found the invention allowable to the extent that it reads on the elected Group and since claims 42-55 recite further limitations on the elected Group, claims 42-55 are allowable.

Issues raised by the Examiner are addressed below in the order they appear in the Office Action. Applicants respectfully request reconsideration in view of the following remarks.

1. Request for Continued Examination Granted

Applicants acknowledge that a request for continued examination has been granted and that the finality of the previous Office Action has been withdrawn. Applicants also note that Applicants' submission filed on September 13, 2004 has been entered.

2. Withdrawn Rejections - Double Patenting

Applicants note with appreciation the withdrawal of the double patenting rejection of claims 1, 15-17, 20, 23, 27, 28, 36-39 over US 6,432,970 in view of the filing of a terminal disclaimer.

3. Claim Rejections – 35 USC 112, First Paragraph – Claims 1, 15-17, 20, 22-23, 27-28, 36-39, and 41

Claims 1, 15-17, 20, 22-23, 27-28, 36-39, and 41 are rejected under 35 USC 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse the rejection to the extent that it is maintained over the claims as amended. Since claims

1, 15-17, 20, 22-23, 27-28, 36-37, and 41 are cancelled, the present rejection is rendered moot for these claims.

The Office contends that “[t]he presently claimed invention as a whole is not adequately described in the present specification because there is a lack of correlation between the recited functions/properties and the structure of compounds called for.” While Applicants disagree for reasons of record, as currently amended, all the pending claims read on the general structures of Formulae I and II and their corresponding substructures Formula Ia and IIa. Applicants submit that the description would lead the skilled artisan to conclude that Applicants had possession of the claimed invention at the time of filing. Applicants submit that the pending claims now correspond to the elected subject matter, which the Examiner has indicated is allowable. Applicants respectfully request that the Office reconsider and withdraw the instant written description rejection of claims 38-39.

4. Claim Rejections – 35 USC 112, First Paragraph – Claims 1, 15-17, 20, 22-23, 27-28, 36-39, and 41

Claims 1, 15-17, 20, 22-23, 27-28, 36-39, and 41 are rejected under 35 USC 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention. Applicants respectfully traverse the rejection to the extent that it is maintained over the claims as amended. Since claims 1, 15-17, 20, 22-23, 27-28, 36-37, and 41 are cancelled, the present rejection is rendered moot for these claims.

The Office asserts that according to MPEP 2164.08 “the scope of enablement must bear a ‘reasonable correlation’ to the scope of the claims. The present specification lacks correlation between the structure of the claimed compounds necessary to practice the claimed invention and the properties recited by the instant claims.” While Applicants disagree for reasons of record, Applicants submit that following entry of the present amendments, the instant claims clearly possess the “reasonable correlation” described by the Examiner. Applicants also note that since the subject matter of the claims as currently amended was indicated as allowable by the Examiner, it is necessarily enabled. Applicants respectfully request that the Office reconsider and withdraw the instant enablement rejection of claims 38-39.

The Office Action maintains the contention that the instant claims are single means claims and states that “[i]n the present situation, the claimed invention covers every conceivable structure having a molecular weight less than 750 amu for achieving the claimed purpose...” While Applicants disagree for reasons of record, Applicants submit that in light of the present amendments, this rejection is moot. Accordingly, Applicants submit that the present claims are not single means claims and respectfully request that the Office reconsider and withdraw the instant enablement rejection of claims 38-39.

5. *Withdrawn Rejections – 35 USC 102(b)*

Applicants note with appreciation the withdrawal of the rejection of claims 1, 20, 36, and 38-39 under 35 USC 102(b) over Gerashchenko et al.

6. *Withdrawn Rejections – 35 USC 103(a)*

Applicants note with appreciation the withdrawal of the rejection of claims 15-17, 22-23, 27-28, and 37 under 35 USC 103(a) over Gerashchenko et al.

7. *Amendments to the Specification*

The Examiner has requested that Applicants update the specification to incorporate the status of the parent applications. Applicants are complying and hereby amend the corresponding paragraph on page 1 of the specification.

**CONCLUSION**

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims are now in condition for allowance and early notification to this effect is earnestly solicited. Any questions arising from this submission may be directed to the undersigned at (617) 951-7000.

If there are any other fees due in connection with the filing of this submission, please charge the fees to our **Deposit Account No. 18-1945**. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit account.

Date: April 14, 2006

**Customer No: 28120**  
Fish & Neave IP Group  
Ropes & Gray LLP  
One International Place  
Boston, MA 02110  
Phone: 617-951-7000  
Fax: 617-951-7050

Respectfully Submitted,



---

David P. Halstead, Ph.D.  
Reg. No. 44,735